

Message Text

UNCLASSIFIED

PAGE 01 STATE 189960
ORIGIN HEW-06

INFO OCT-01 AF-10 EUR-12 ISO-00 OES-09 EB-08 COME-00
/046 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/NE RWOODS(INFO)
AF/S:JTAYLOR(INFO)
EUR/NE:SWORREL(INFO)
EUR/NE:WNEWLIN(INFO)
EUR/WE:AHUGHES(INFO)

-----107999 272140Z /61

P 272036Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY THE HAGUE PRIORITY

UNCLAS STATE 189960

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, SU, SF, UK, BE, SP, NL

SUBJECT: FDA ADVISORY - FIRM INITIATED "RECALL" OF
ELECTROSURGICAL UNIT (RECALL T-095-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - SOLID STATE ELECTROSURGICAL UNIT (POWER
GENERATOR) IN HARD PLASTIC ENCLOSURE, LABELED IN PART
...ASPEN LABS...MF 360...ASPEN LABS INC.....LITTLETON,
COLORADO...".

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2. PRODUCT IDENTIFICATION - (A) AS ABOVE. ADDRESS AND
NAME OF FIRM ON LABEL IS THAT OF MANUFACTURER.
(B) MODEL MF 360, WITH ONE OF APPROXIMATELY 200 SERIAL
NUMBERS. SERIAL NUMBERS CONSIST OF TWO ALPHA DIGITS
FOLLOWED BY TWO NUMBERS, THEN EITHER A SLASH AND TWO MORE
NUMBERS, OR NO SLASH AND THREE NUMBERS. EXAMPLE AF02/76

OR BE08771.

-

RECALL EXTENDS TO ALL SERIAL NUMBERS PRIOR TO BA09771. THE CODE IS BROKEN DOWN INTO LOT (FIRST ALPHA DIGIT). UNIT WITHIN LOT (SECOND ALPHA DIGIT), MONTH (TWO NUMBERS), YEAR (TWO NUMBERS), AND IN CERTAIN CASES, THE NUMBER "1" WHICH DESIGNATES THE MODEL NUMBER.

3. MANUFACTURING FIRM/RECALLING FIRM:

ASPEN LABS INC., 2430 WEST ALAMO AVE., LITTLETON, COLORADO

4. REASON FOR RECALL RECOMMENDATION:

FDA WAS ALERTED TO THE RECALL THROUGH AN ARTICLE IN A MEDICAL DEVICE JOURNAL THAT STATED A HOSPITAL REPORTED THE ASPEN LABS ELECTROSURGICAL UNIT REMAINED ACTIVATED UPON RELEASE OF THE CUT SWITCH.

5. IT ALSO STATED THAT THE UNIT BECOMES DEACTIVATED IF THE ACTIVE ELECTRODE CONTACTS TISSUE. BUT COULD DELIVER SUFFICIENT ENERGY TO BURN BEFORE DEACTIVATION. THE ARTICLE STATED THAT TESTS PERFORMED ON THE UNIT HAD CONFIRMED THE PROBLEM, CITING THAT THE PROBLEM CAME FROM INADEQUATE FILTERING IN THE CUT MODE SWITCHING CIRCUIT. FOREIGN CONSIGNEES WERE NOTIFIED BY LETTER DATED DECEMBER 15, 1977 INDICATING PROBLEM, PROVIDING INSTRUCTIONS ON HOW TO MODIFY AFFECTED UNITS, ACCOMPANIED UNCLASSIFIED

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BY NECESSARY PARTS FOR MODIFICATION, AND FORMALLY REQUESTING CONSIGNEE TO INDICATE TO FIRM THAT THEY HAD SUCCESSFULLY PERFORMED NECESSARY MODIFICATIONS.

6. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED LETTER, PARTS AND MODIFICATION INSTRUCTIONS. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE REFERRED TO FIRM DIRECTLY.

7. CONSIGNEES AS FOLLOWS:

AB BIOTEC: SOLNA, SWEDEN

BIO-ENGINEERING SERVICES: JOHANNASBURG, SOUTH AFRICA

GENITO-URINARY MFG. CO. LTD.: LONDON, ENGLAND

LA DYNAMIQUE APPLIQUE S.A.: BRUSSELS, BELGIUM (REFERRED BY I.B.S. PARIS, FRANCE)

MEDTRIONIKA: BARCELONA, SPAIN

STOPLER INSTRUMENTEN AND APPARATEN B.U.: UTRECHT, HOLLAND
CHRISTOPHER

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PAGE 01 STATE 189960
ORIGIN EUR-12

INFO OCT-01 ISO-00 /013 R

66011

DRAFTED BY:EUR/WE:AHUGHES

APPROVED BY:EUR/WE:RPAGANELLI

-----069479 030806Z /10

R 030745Z AUG 78

FM SECSTATE WASHDC

TO AMCONSUL BARCELONA

UNCLAS STATE 189960

FOLLOWING REPEAT STATE 189960 ACTION STOCKHOLM PRETORIA
LONDON BRUSSELS MADRID THE HAGUE JULY 27.

QUOTE: UNCLAS STATE 189960

E.O. 11652: N/A

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CHRISTOPHER UNQUOTE VANCE

ORIG DIST: EUR,OES,EB,COME,HEW/ISO,AF.

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: ELECTRONIC EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 27 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE189960
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780308-1165
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780713/aaaaakpi.tel
Line Count: 232
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 6925d76b-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1864436
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FIRM INITIATED "RECALL" OF ELECTROSURGICAL UNIT (RECALL T-095-8)
TAGS: OGEN, ETRD, EIND, TBIO, SU, SF, UK, BE, SP, NL, ASPEN LABS INC
To: STOCKHOLM PRETORIA MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/6925d76b-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014